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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,366	09/26/2006	Arthur E. Uber III	IN/04-002PCT.US	7429

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EXAMINER

LEE, BENJAMIN HYOUNGSOL

ART UNIT	PAPER NUMBER
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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,366	Applicant(s) UBER ET AL.	
	Examiner BENJAMIN LEE	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 21-29 and 45-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 30-37, 39-44 and 51-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to the amendment filed on 6/1/2010, claims 18-20, 30-37, 39-44 and 51-56 are being examined, and claim 38 has been canceled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 18-20, 30-36 and 42** are rejected under 35 U.S.C. 102(b) as being anticipated by Giba et al. (5,876,373).

As to claim 18, Giba discloses in Figs. 9A and 9B a device for penetrating tissue and positioning a catheter, comprising: a catheter 100 comprising a passage therethrough (see distal end of catheter in Fig. 9A); and a penetrator 214 in operative connection with the catheter, the penetrator capable of being energized with mechanical energy (e.g. spring, see col. 11, lines 29-45) in a repetitive manner (e.g. by applying pressure to plate 200 repeatedly) to assist in penetrating tissue (col. 11, lines 29-45).

As to claim 19, Giba discloses the penetrator is removably positioned within the passage of the catheter (e.g. by removing threadable end cap 202, see col. 11, lines 12-14).

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As to claim 20, Giba discloses the penetrator is positioned on the exterior of the catheter when extended (see Fig. 9B).

As to claim 30, Giba discloses a method of inserting a tissue resident conduit (e.g. catheter 100) into tissue, comprising the step: energizing at least a portion of a forward end of the conduit insertion device (e.g. piercing tube 214) with mechanical energy (e.g. spring) to assist in penetrating tissue (col. 11, lines 29-45).

As to claim 31, Giba discloses the tissue resident conduit is a catheter (col. 11, lines 29-45).

As to claim 32, Giba discloses the tissue resident conduit is flexible (e.g. deflectable, see abstract).

As to claim 33, Giba discloses the tissue resident conduit has a blunt forward surface 118 (see Fig. 9A).

As to claim 34, Giba discloses a device for inserting a tissue resident conduit (e.g. catheter 100) comprising: at least one component 214 that is energized with mechanical energy (e.g. spring) during penetration to assist in penetrating tissue (col. 11, lines 29-45).

As to claim 35, Giba discloses the tissue resident conduit is flexible (e.g. deflectable, abstract) and the energized component is positioned on a forward end of the tissue resident conduit (see Fig. 9B).

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As to claim 36, Giba discloses a mechanism (e.g. steering) capable of directing the penetration of the tissue resident conduit (col. 8, lines 13-18).

As to claim 42, Giba discloses the tissue resident conduit is a catheter (col. 11, lines 29-45).

4. **Claims 34, 37, 39-41 and 43-44** are rejected under 35 U.S.C. 102(b) as being anticipated by Cosman et al. (USPN 6,478,793).

As to claim 34, Cosman discloses a device in Fig. 3 for inserting a tissue resident conduit 142 comprising: at least one component 184 that is energized with mechanical energy (e.g. motor) during penetration (col. 7, lines 15-26) to assist in penetrating tissue (e.g. by ablation).

As to claim 37, Cosman discloses a rigid penetrator 184, the energized component being positioned on a forward end of the penetrator (since the entire penetrator 184 is an electrode), the tissue resident conduit being in operative and removable connection with the penetrator so that the penetrator can be removed from penetrated tissue while the tissue resident conduit remains within the penetrated tissue (col. 7, lines 47-50).

Note that the penetrator is inserted into the tissue resident conduit 142 and is capable of being removed due to the feature of the invention where various types of stylets may be interchanged depending on the user's preference. Note that penetrator 184 (e.g. cannula) is generally within the penetrated tissue and remains (col. 8, lines 39-47), and is capable of the required functional language of the claim. In an alternative

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interpretation, the rigid penetrator may be element 142 and the tissue resident conduit may be element 184.

As to claim 39, Cosman discloses the penetrator is positioned within the conduit during penetration (see arrows of Fig 3).

As to claim 40, Cosman discloses the tissue resident conduit is positioned adjacent the penetrator during penetration (since when the penetrator is inside the conduit, the penetrator is also adjacent the conduit).

As to claim 41, Cosman discloses the tissue resident conduit is flexible (col. 7, lines 59-64).

As to claim 43, the tissue resident conduit of Cosman is a catheter since it's a tube inserted into the body and is capable of keeping a passage open.

As to claim 44, Cosman discloses an effector 184 that is capable of penetrating through a wall of a blood vessel (col. 7, lines 53-56).

5. **Claims 51-53** are rejected under 35 U.S.C. 102(b) as being anticipated by Sadaat et al. (6,120,520).

As to claim 51, Saadat discloses in Figs. 5, 6 and 8 a non-coring needle comprising a penetrating member 61 (the needle is the penetrating member, col. 6, lines 2-3) that is energized with mechanical energy (col. 8, lines 4-7), a forward end of the penetrating member comprising a forward extending section comprising at least two points spaced from each other and being adapted to pierce tissue. Note that the term "two points" is extremely broad and does not necessarily require two sharpened points in the manner

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of Fig. 11e of Applicant's drawings. Two points may be broadly interpreted as having an arbitrary two points on the forward section of the penetrating member. Furthermore, needles with two sharpened points are known in the art (see Citation of Pertinent Art below).

As to claim 52, Saadat discloses an actuator 26 (e.g. controller) to energize at least a portion of the needle (e.g. electrodes 42a-b) to facilitate penetration (col. 7, lines 44-50). Note that language "to facilitate penetration" is functional language that the needle of Saadat is capable of since it emits RF energy.

As to claim 53, Saadat inherently discloses at least a portion of the forward end of the penetrating member is non-cutting so that coring does not occur upon penetration of the tissue since the needle is non-coring (col. 6, lines 2-3).

6. **Claims 55-56** are rejected under 35 U.S.C. 102(b) as being anticipated by Unsworth (6,520,927).

As to claim 55, Unsworth discloses a blunt needle (col. 6, lines 57-59) comprising at least one effector 4 that does not readily penetrate tissue and at least one actuator 3 that when energized with mechanical energy (via motor 2) enables the needle to readily penetrate tissue (col. 6, lines 36-41).

As to claim 56, Unsworth discloses a conduit such that fluid can be delivered to the tissue or material removed from the tissue since the needle is hollow (col. 6, lines 54-55).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. **Claim 54** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (6,702,790)

As to claim 54, Sadaat does not expressly disclose at least two points are positioned to stabilize tissue for penetration. However, to have implemented the claimed feature in the penetrator of Saddat would have been obvious to one of ordinary skill in the art since Ross discloses the claimed feature (Fig. 4, col. 3, lines 29-31) and in order to enhance penetration (col. 2, lines 12-17).

Response to Arguments

Applicant's arguments with respect to claims 18-20, 30-37, 39-44 and 51-56 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./ 7/28/2010
Examiner, Art Unit 3739

/Thomas J Sweet/

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Supervisory Patent Examiner, Art Unit 3739